ISRCTN07452238 https://doi.org/10.1186/ISRCTN07452238

A study to determine the cardiovascular effects of different methods of administering the oxytocic drug Syntocinon

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
12/05/2009

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0047119214

Study information

Scientific Title

Study objectives
Can we decrease the unwanted effects of syntocinon, namely hypotension and tachycardia, by slowing down the rate of injection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective randomised controlled single-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Anaesthesia

Interventions
Bolus injection (bolus group) vs infusion over 5 min (infusion group)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
syntocinon

Primary outcome measure

Reason for study ie to determine a method that can be used to routinely limit the decrease in blood pressure.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2002

Completion date
31/01/2006

Eligibility

Key inclusion criteria
Women choosing spinal anaesthesia for elective Caesarean:
15 in control group receiving syntocinon 5 units intravenously (IV) as a bolus after delivery 15 in study group receiving syntocinon 5 units IV continuously over 5 min after delivery

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
30

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/11/2002

Date of final enrolment
31/01/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Anaesthesia
Birmingham
United Kingdom
B15 2TG

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Birmingham Women's Healthcare NHS Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2007		Yes	No